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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,832	01/25/2002	Max Costa	5986/1I147US1	1550

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EXAMINER	
UNGAR, SUSAN NMN	

ART UNIT	PAPER NUMBER
1642	8

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/057,832	Costa et al
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *one* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 25, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-102* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-102* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-102 are pending in the application and are currently under prosecution.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claims 1, 13, 25, 38, 51 link inventions 1-4/(A)-(H) and 5-12. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 13, 25, 38, 51. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is

withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1, 3-7, 9-11, 25-35 drawn to an *in situ* method for identifying/diagnosing a diseased cell or tissue said disease being associated with elevated CAP43 protein expression, classified in Class 435, subclasses 4 and 7.1.

Group 2. Claims 1, 3-6, 8, 9-11, 25 drawn to an *in vivo* method for identifying/diagnosing a diseased cell or tissue said disease being associated with elevated CAP43 protein expression, classified in Class 424, subclass 130.1.

Group 3. Claims 1-2, 13-19, 21-23, 25 drawn to an *in situ* method for identifying/diagnosing a diseased cell or tissue said disease being associated with elevated CAP43 nucleic acid expression, classified in Class 435, subclass 6.

Group 4. Claims 1-2, 13-18, 20-23 drawn to an *in vivo* method for identifying/diagnosing a diseased cell or tissue said disease being associated with elevated CAP43 nucleic acid expression, classified in Class 536, subclass 23.1.

For each of the inventions 1-4 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 1-4 **and** one of inventions (A)-(H). It is noted that this is not an election of species

requirement in that each of the linked groups consists of one of inventions 1-4 above **and** one of inventions (A)-(H) below.

(A) lung cancer

(B) colon cancer

©) kidney cancer

(D) breast cancer

(E) prostate cancer

(F) melanoma

(G) lymphoma

(H) malignant fibrous histocytoma

Group 5. Claims 1, 11, 13, 23, 25, 37, 38, 50 are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is granuloma, comprising assaying for elevated CAP43 polypeptide *in vitro*, as disclosed, classified in Class 435, subclasses 4 and 7.1.

Group 6. Claims 1, 11, 13, 23, 25, 37, 38, 50 are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is granuloma, comprising assaying for elevated CAP43 polypeptide *in vivo*, as disclosed, classified in Class 424, subclasses 130.1.

Group 7. Claims 1, 11, 13, 23, 25, 37, 38, 50 are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is granuloma, comprising assaying for elevated CAP43 polynucleotide *in vitro*, as disclosed, classified in Class 435, subclass 6.

Group 8. Claims 1, 11, 13, 23, 25, 37, 38, 50 are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is granuloma, comprising assaying for elevated CAP43 polynucleotide *in vivo*, as disclosed, classified in Class 536, subclass 23.1.

Group 9. Claims 1, 12-13, 24-25, 36, 38, 49, are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is atherosclerosis, comprising assaying for elevated CAP43 polypeptide *in vitro*, as disclosed, classified in Class 435, subclasses 4 and 7.1.

Group 10. Claims 1, 12-13, 24-25, 36, 38, 49, are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is atherosclerosis, comprising assaying for elevated CAP43 polypeptide *in vivo*, as disclosed, classified in Class 424, subclass 130.1.

Group 11. Claims 1, 12-13, 24-25, 36, 38, 49, are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is atherosclerosis, comprising assaying for elevated CAP43 nucleic acid *in vitro*, as disclosed, classified in Class 435, subclass 6.

Group 12. Claims 1, 12-13, 24-25, 36, 38, 49, are drawn to a method for identifying/diagnosing a diseased cell or tissue, wherein said disease is atherosclerosis, comprising assaying for elevated CAP43 nucleic acid *in vivo*, as disclosed classified in Class 536, subclass 23.1.

4. Claims 59 and 62 link inventions 13-14/(A)-(R)/(I)-(vii), 15-18. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 59 and 62. Upon the allowance of the linking claim(s),

the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 13. Claims 59-71 are drawn to a method for administering a compound to a diseased cell associated with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that specifically binds to a CAP43 polypeptide *in vitro* as disclosed, classified in Class 435, subclass 4.

Group 14 Claims 59-71 are drawn to a method for administering a compound to a diseased cell associated with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that specifically binds to a CAP43 polypeptide *in vivo* as disclosed, classified in Class 424, subclass 130.1.

For each of the inventions 13-14 above, restriction to one of the following is also required under 35 USC121.

(A) thymidine kinase

(B) endonuclease

(C) RNAse

(D) alpha-toxin

(E) ricin

(F) abrin

(G) exotoxin A

(H) diptheria toxin

(I) saporin

(J) momordin

(K) gelonin

(L)pokeweek antiviral protein

(M) alpha-sarcin

(N) cholera toxin

(O) benzoic acid mustard alkylating agent derivative/glutamyl derivative of benzoid acid mustard alkylating agent

(P) etoposide derivative/phosphate derivative of etoposide

(Q) mitomycin C derivative/phosphate derivative of mitomycin C

(R) doxorubicin derivative/phenoxyacetamide derivative of doxorubicin

For each of the inventions 13-14 and (A)-(R) above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 13-14 **and** one of inventions (A)-(R) **and** one of inventions (i)-(vii). It is noted that this is not an election of species requirement in that each of the linked

groups consists of one of inventions 1-4 **and** one of inventions (A)-(R) above **and** one of inventions (i)-(vii) below.

(i) lung cancer

(ii) kidney cancer

(iii) breast cancer

(iv) prostate cancer

(v) melanoma

(vi) lymphoma

(vii) malignant fibrous histocytoma

Group 15. Claims 59 and 72 are drawn to a method for administering a compound to an atherosclerotic cell associated with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that specifically binds to a CAP43 polypeptide *in vitro* as disclosed, classified in Class 435, subclass 4.

Group 16 Claims 59 and 72 are drawn to a method for administering a compound to an atherosclerotic cell with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that specifically binds to a CAP43 polypeptide *in vivo* as disclosed, classified in Class 424, subclass 130.1.

Group 17. Claims 59 and 73 are drawn to a method for administering a compound to a granuloma cell associated with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that

specifically binds to a CAP43 polypeptide *in vitro* as disclosed, classified in Class 435, subclass 4.

Group 18 Claims 59 and 73 are drawn to a method for administering a compound to a granuloma cell associated with abnormal CAP43 expression comprising contacting the cell with the compound complexed to a protein that specifically binds to a CAP43 polypeptide *in vivo* as disclosed, classified in Class 424, subclass 130.1.

5. Claims 74 and 76 link inventions 99-37. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 74 and 76. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 19-35. Claims 74-83 are drawn to a complex/pharmaceutical composition comprising an antibody, that specifically binds to CAP43 polypeptide, complexed to one of the seventeen therapeutic compounds

recited in claims 76-78, that is thymidine kinase, endonuclease, RNAse, alpha-toxin, ricin, abrin, exotoxin A, diptheria toxin, saporin,momordin, gelonin, pokeweek antiviral protein, alpha-sarcin, cholera toxin, benzoic acid mustard alkylating agent derivative, etoposide derivative, mitomycin C derivative, doxorubicin derivative each of which is a distinct invention classified in Class 424, subclass 130.1. It is noted that **this is not an election of species requirement**. Applicant must elect a single invention for examination

Group 36. Claims 84-85, 87-88, 97-99 are drawn to a kit and pharmaceutical composition comprising a nucleic acid, classified in Class 536, subclass 23.1.

Group 37. Claims 84, 86-88, 100-102 are drawn to a kit comprising an antibody/pharmaceutical composition classified in Class 530, subclass 387.1.

6. Claim 89 links inventions 38-39. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 89. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 38 Claims 89-92 are drawn to a method for treating a disorder associated with abnormal expression of CAP43, comprising contacting the cell with a compound that inhibits expression of a CAP43 nucleic acid, classified in Class 536, subclass 23.1.

Group 39 Claims 89-92 are drawn to a method for treating a disorder associated with abnormal activity of CAP43, comprising contacting the cell with a compound that inhibits activity of a CAP43 nucleic acid, classified in Class 536, subclass 23.1.

For each of the inventions 38-39 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 38-39 **and** one of inventions (A)-(I). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 38-39 above **and** one of inventions (A)-(H) below.

(A) lung cancer

(B) colon cancer

©) kidney cancer

(D) breast cancer

(E) prostate cancer

(F) melanoma

(G) lymphoma

(H) malignant fibrous histocytoma

7. Claim 93 links inventions 40-41. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 93. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 40 Claims 93-96 are drawn to a method for treating a disorder associated with abnormal expression of CAP43, comprising contacting the cell with a compound that inhibits expression of a CAP43 polypeptide, classified in Class 424, subclass 130.1.

Group 41 Claims 93-96 are drawn to a method for treating a disorder associated with abnormal activity of CAP43, comprising contacting the cell with a compound that inhibits activity of a CAP43 nucleic acid, classified in Class 424, subclass 130.1.

For each of the inventions 40-41 above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions 40-41 **and** one of inventions (A)-(H). It is noted that this is not an election of species requirement in that each of the linked groups consists of one of inventions 40-41 above **and** one of inventions (A)-(H) below.

(A) lung cancer

(B) colon cancer

©) kidney cancer

(D) breast cancer

(E) prostate cancer

(F) melanoma

(G) lymphoma

(H) malignant fibrous histocytoma

8. The inventions are distinct, each from the other because of the following reasons:

Inventions 19-37 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 1-18 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

The inventions of Groups 19-35 and 13-18 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following

can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody conjugate product as claimed can be used in a materially different process such as producing an antibody against the conjugate for removing the conjugate from an in vivo system.

The inventions of Groups 37 and 1, 2, 5, 6, 9, 10 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the antibody conjugate product as claimed can be used in a materially different process such as the production of anti-idiotypic antibodies.

The inventions of Groups 36 and 3, 4, 7, 8,11, 12 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § **806.05(h)**]. In the instant case the nucleic acid as claimed can be used to produce the polypeptide encoded by the nucleic acid.

The inventions of Groups 1, 2, 5, 6, 9, 10, 13-18 and 36 are not at all related because the methods of Groups 1, 2, 5, 6, 9, 10, 13-18 do not use the nucleic acid product of Group 36.

The inventions of Groups 1, 2, 5, 6, 9, 10 and 19-35 are not at all related because the methods of Groups 1, 2, 5, 6, 9, 10 do not use the conjugates of Groups 19-35.

The inventions of Groups 13-18 and 37 are not at all related because the methods of Groups 13-18 do not use the antibody of Group 37.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar
Primary Patent Examiner
October 2, 2003